



CLINICAL EVALUATION SUMMARY OF RAPID RESPONSE™ COVID-19 ANTIGEN RAPID TEST DEVICE (NASOPHARYNGEAL/OROPHARYNGEAL SWAB)

Rapid Response™ COVID-19 Antigen Rapid Test Device clinical trials were performed at two sites in China from February 28, 2020 to April 8, 2020. These clinical trials were aimed to evaluate the performance of Rapid Response™ COVID-19 Antigen Rapid Test Device by comparing with RT-PCR for the intended use of detecting SARS-CoV-2 viral antigens in patients within two weeks of symptom onset.

1 CLINICAL TRIAL LOCATION:

Site 1: The First Hospital of Zhejiang Province

Site 2: Zhejiang Provincial Center for Disease Control and Prevention

2 CLINICAL SPECIMENS

The following specimen were included in this study:

85 prospective clinical specimens were collected from Site 1 which included 43 specimens of nasopharyngeal swab and 42 specimens of oropharyngeal swab. Individuals who were suspected of COVID-19 within 14 days of symptom onset were enrolled in this study (Including those who had contact with a confirmed patient or had visited a disease outbreak area). At the time of sample collection, some people exhibited mild (e.g. low fever, cough, fatigue) or severe (e.g. High fever, chest tightness, weakness) symptoms. 55 positive specimens and 30 negative specimens were confirmed by RT-PCR. There were 41 positive samples with $Ct < 30$, and 14 positive samples with $Ct \geq 30$.

131 retrospective clinical specimen who are either asymptomatic or with mild symptoms (within 14 days of symptom onset) were collected to confirm the specificity. All of these are confirmed negative through PCR. 59 specimens were of nasopharyngeal swab and 72 specimens of oropharyngeal swab.

49.1% of the donors were male, and 50.9% were female.

3 METHODS

Rapid Response™ COVID-19 Antigen Rapid Test Device was used to run the clinical specimens collected. Each specimen was tested according to IFU. The results were recorded and compared with the results obtained by RT-PCR.

4 COMMERCIAL KITS USED FOR COMPARISON

RT-PCR instrument ABI7500 (reagent Lot No.: 20200114A, exp. date: 2021-01-13, manufactured by Shanghai BioGerm Medical Biotechnology Co., Ltd).

- Limit of Detection: 1000 copies/ml
- Cross-reactivity was assessed against the below pathogens:

Influenza A (H1N1/H1N1(2009)/H3N2/H5N1/H7N9)	Human partial pulmonary virus	Staphylococcus aureus
Influenza B (BV/BY)	Rotavirus	Streptococcus pneumoniae
Human coronavirus (229E/HKU1/OC43/NL63/SARS/MERS)	Norovirus	Mycobacterium tuberculosis
Parainfluenza(1/2/3)	Varicella-Zoster virus	Streptococcus pyogenes
Rhinovirus(A/B/C)	Mumps virus	Klebsiella pneumoniae
Bocavirus	Chlamydia pneumoniae	Aspergillus fumigatus
RSV	Mycoplasma pneumoniae	Candida albicans
EBV	Legionella	Candida glabrata
Measles Virus	Bordetella pertussis	Cryptococcus neoformans
Human cytomegalovirus	Haemophilus influenzae	Adenovirus 1/2/3/4/5/7/55



5 TEST RESULTS

a) Clinical data

Clinical sample number	Site	Age	Gender	Sample Type	Symptoms (mild/severe)	Time of symptom onset	Days between symptom onset and specimen collection for Rapid test	Days between symptom onset and specimen collection for PCR test	PCR test result	PCR Ct Value	Rapid test result
1	Site 1	23	Female	NP	mild	2020-02-26	3	3	-	NA	-
2	Site 1	23	Female	OP	mild	2020-02-26	3	3	-	NA	-
3	Site 1	47	Male	NP	mild	2020-02-29	1	1	-	NA	-
4	Site 1	60	Female	NP	mild	2020-03-01	1	1	-	NA	-
5	Site 1	56	Female	NP	mild	2020-03-01	2	2	-	NA	-
6	Site 1	47	Male	OP	mild	2020-02-22	12	12	+	21	+
7	Site 1	60	Female	OP	mild	2020-03-04	1	1	-	NA	-
8	Site 1	42	Male	NP	mild	2020-03-05	1	1	-	NA	-
9	Site 1	42	Male	OP	mild	2020-03-05	1	1	-	NA	-
10	Site 1	61	Female	NP	mild	2020-03-05	1	1	-	NA	-
11	Site 1	55	Female	NP	mild	2020-03-07	1	1	-	NA	-
12	Site 1	62	Male	OP	mild	2020-03-07	2	2	-	NA	-
13	Site 1	28	Female	NP	mild	2020-03-08	1	1	-	NA	-
14	Site 1	47	Male	NP	mild	2020-03-08	2	2	-	NA	-
15	Site 1	47	Male	NP	mild	2020-03-08	2	2	-	NA	-
16	Site 1	84	Male	NP	mild	2020-03-08	2	2	-	NA	-
17	Site 1	50	Female	OP	mild	2020-03-09	2	2	-	NA	-
18	Site 1	26	Female	OP	mild	2020-03-01	11	11	+	24	+
19	Site 1	37	Female	OP	mild	2020-03-10	4	4	+	23	+
20	Site 1	45	Female	NP	mild	2020-03-06	9	9	+	23	+
21	Site 1	53	Female	OP	mild	2020-03-01	14	14	+	22	+
22	Site 1	60	Female	OP	mild	2020-03-13	3	3	-	NA	-



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Clinical Evaluation Summary
Rapid Response™ COVID-19 Antigen Rapid Test Device
(Nasopharyngeal/Oropharyngeal)
COV-19C25

Clinical sample number	Site	Age	Gender	Sample Type	Symptoms (mild/severe)	Time of symptom onset	Days between symptom onset and specimen collection for Rapid test	Days between symptom onset and specimen collection for PCR test	PCR test result	PCR Ct Value	Rapid test result
23	Site 1	47	Male	OP	mild	2020-03-15	1	1	-	NA	-
24	Site 1	60	Female	NP	mild	2020-03-13	3	3	-	NA	-
25	Site 1	47	Male	NP	mild	2020-03-15	1	1	-	NA	-
26	Site 1	30	Female	NP	mild	2020-03-05	12	12	+	24	+
27	Site 1	30	Female	OP	mild	2020-03-09	8	8	+	35	-
28	Site 1	49	Male	OP	mild	2020-03-14	3	3	-	NA	-
29	Site 1	54	Female	OP	mild	2020-03-15	2	2	-	NA	-
30	Site 1	64	Female	NP	mild	2020-03-16	2	2	-	NA	-
31	Site 1	21	Male	NP	mild	2020-03-16	2	2	-	NA	-
32	Site 1	50	Female	NP	mild	2020-03-17	2	2	-	NA	-
33	Site 1	44	Male	NP	mild	2020-03-07	13	13	+	22	+
34	Site 1	53	Female	OP	mild	2020-03-06	14	14	+	23	+
35	Site 1	56	Female	NP	mild	2020-03-18	2	2	-	NA	-
36	Site 1	56	Male	OP	mild	2020-03-18	2	2	-	NA	-
37	Site 1	74	Male	NP	mild	2020-03-18	2	2	-	NA	-
38	Site 1	74	Male	OP	mild	2020-03-18	2	2	-	NA	-
39	Site 1	40	Female	OP	mild	2020-03-19	3	3	-	NA	-
40	Site 1	48	Male	NP	mild	2020-03-10	13	13	+	21	+
41	Site 1	76	Male	OP	mild	2020-03-17	13	13	+	24	+
42	Site 1	70	Female	NP	mild	2020-03-20	10	10	+	22	+
43	Site 1	48	Male	NP	mild	2020-03-21	9	9	+	20	+
44	Site 1	30	Female	OP	mild	2020-03-18	13	13	+	21	+
45	Site 1	47	Female	OP	mild	2020-03-22	9	9	+	22	+
46	Site 1	71	Female	OP	mild	2020-03-19	12	12	+	22	+
47	Site 1	39	Female	OP	mild	2020-03-19	12	12	+	32	+
48	Site 1	10	Male	OP	mild	2020-03-18	13	13	+	37	+



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Clinical Evaluation Summary
Rapid Response™ COVID-19 Antigen Rapid Test Device
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COV-19C25

Clinical sample number	Site	Age	Gender	Sample Type	Symptoms (mild/severe)	Time of symptom onset	Days between symptom onset and specimen collection for Rapid test	Days between symptom onset and specimen collection for PCR test	PCR test result	PCR Ct Value	Rapid test result
49	Site 1	64	Female	OP	mild	2020-03-21	11	11	+	22	+
50	Site 1	55	Female	OP	mild	2020-03-18	14	14	+	21	+
51	Site 1	67	Female	NP	mild	2020-03-27	5	5	+	24	+
52	Site 1	28	Male	NP	mild	2020-03-23	9	9	+	20	+
53	Site 1	11	Male	NP	mild	2020-03-18	14	14	+	31	+
54	Site 1	59	Male	NP	mild	2020-03-21	11	11	+	36	+
55	Site 1	49	Male	NP	mild	2020-03-20	12	12	+	30	+
56	Site 1	69	Male	OP	mild	2020-03-19	13	13	+	34	-
57	Site 1	28	Female	NP	mild	2020-03-27	6	6	+	24	+
58	Site 1	80	Female	OP	mild	2020-03-21	12	12	+	21	+
59	Site 1	30	Female	OP	mild	2020-03-19	14	14	+	21	+
60	Site 1	40	Male	NP	mild	2020-03-22	11	11	+	30	+
61	Site 1	63	Male	NP	mild	2020-03-23	10	10	+	37	-
62	Site 1	81	Male	OP	mild	2020-03-28	6	6	+	22	+
63	Site 1	38	Male	OP	mild	2020-03-21	13	13	+	22	+
64	Site 1	52	Male	NP	mild	2020-03-21	13	13	+	23	+
65	Site 1	40	Female	NP	mild	2020-03-25	9	9	+	21	+
66	Site 1	44	Female	NP	mild	2020-03-21	13	13	+	32	+
67	Site 1	46	Female	NP	mild	2020-03-23	11	11	+	25	+
68	Site 1	56	Female	NP	mild	2020-03-20	14	14	+	37	+
69	Site 1	70	Male	OP	mild	2020-03-25	10	10	+	21	+
70	Site 1	38	Female	OP	mild	2020-03-23	12	12	+	21	+
71	Site 1	52	Female	OP	mild	2020-04-01	4	4	+	24	+
72	Site 1	48	Male	NP	mild	2020-03-30	6	6	+	21	+
73	Site 1	38	Male	NP	mild	2020-03-23	13	13	+	20	+
74	Site 1	56	Male	OP	mild	2020-03-24	12	12	+	21	+



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COV-19C25

Clinical sample number	Site	Age	Gender	Sample Type	Symptoms (mild/severe)	Time of symptom onset	Days between symptom onset and specimen collection for Rapid test	Days between symptom onset and specimen collection for PCR test	PCR test result	PCR Ct Value	Rapid test result
75	Site 1	45	Male	OP	mild	2020-04-02	4	4	+	22	+
76	Site 1	39	Male	NP	mild	2020-03-28	9	9	+	21	+
77	Site 1	40	Female	OP	mild	2020-03-31	6	6	+	24	+
78	Site 1	67	Female	NP	mild	2020-03-23	14	14	+	33	+
79	Site 1	79	Female	NP	mild	2020-04-01	6	6	+	22	+
80	Site 1	65	Male	OP	mild	2020-03-24	14	14	+	21	+
81	Site 1	48	Female	OP	mild	2020-03-26	12	12	+	23	+
82	Site 1	34	Female	OP	mild	2020-03-26	12	12	+	24	+
83	Site 1	83	Male	OP	severe	2020-03-31	7	7	+	20	+
84	Site 1	49	Male	OP	mild	2020-03-26	12	12	+	31	+
85	Site 1	70	Male	NP	mild	2020-03-27	11	11	+	35	+
1	Site 2	59	Male	NP	mild	2020-02-26	3	1	-	NA	-
2	Site 2	67	Male	OP	NA	NA	NA	NA	-	NA	-
3	Site 2	49	Male	OP	NA	NA	NA	NA	-	NA	-
4	Site 2	39	Male	OP	NA	NA	NA	NA	-	NA	-
5	Site 2	27	Male	OP	NA	NA	NA	NA	-	NA	-
6	Site 2	57	Female	NP	mild	2020-02-27	3	3	-	NA	-
7	Site 2	42	Female	OP	NA	NA	NA	NA	-	NA	-
8	Site 2	40	Female	OP	NA	NA	NA	NA	-	NA	-
9	Site 2	41	Male	NP	NA	NA	NA	NA	-	NA	-
10	Site 2	58	Male	OP	mild	2020-02-29	1	1	-	NA	-
11	Site 2	29	Male	NP	mild	2020-02-29	1	1	-	NA	-
12	Site 2	35	Female	NP	mild	2020-02-28	3	3	-	NA	-
13	Site 2	29	Female	OP	NA	NA	NA	NA	-	NA	-
14	Site 2	68	Male	OP	NA	NA	NA	NA	-	NA	-
15	Site 2	39	Female	OP	NA	NA	NA	NA	-	NA	-



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16	Site 2	43	Female	NP	mild	2020-03-01	2	2	-	NA	-
17	Site 2	39	Male	OP	mild	2020-03-02	0	0	-	NA	-
18	Site 2	27	Female	OP	mild	2020-03-01	1	1	-	NA	-
19	Site 2	39	Male	NP	mild	2020-03-02	0	0	-	NA	-
20	Site 2	57	Female	NP	mild	2020-02-29	2	2	-	NA	-
21	Site 2	28	Male	NP	NA	NA	NA	NA	-	NA	-
22	Site 2	55	Male	OP	NA	NA	NA	NA	-	NA	-
23	Site 2	65	Female	NP	mild	2020-03-02	2	0	-	NA	-
24	Site 2	40	Female	OP	NA	NA	NA	NA	-	NA	-
25	Site 2	72	Male	OP	NA	NA	NA	NA	-	NA	-
26	Site 2	68	Male	OP	NA	NA	NA	NA	-	NA	-
27	Site 2	27	Female	OP	NA	NA	NA	NA	-	NA	-
28	Site 2	69	Male	OP	NA	NA	NA	NA	-	NA	-
29	Site 2	43	Female	OP	NA	NA	NA	NA	-	NA	-
30	Site 2	29	Male	OP	NA	NA	NA	NA	-	NA	-
31	Site 2	57	Male	OP	NA	NA	NA	NA	-	NA	-
32	Site 2	43	Male	OP	NA	NA	NA	NA	-	NA	-
33	Site 2	47	Male	OP	NA	NA	NA	NA	-	NA	-
34	Site 2	27	Male	OP	NA	NA	NA	NA	-	NA	-
35	Site 2	58	Male	OP	NA	NA	NA	NA	-	NA	-
36	Site 2	55	Female	NP	NA	NA	NA	NA	-	NA	-
37	Site 2	48	Female	OP	NA	NA	NA	NA	-	NA	-
38	Site 2	48	Female	NP	NA	NA	NA	NA	-	NA	-
39	Site 2	58	Male	NP	mild	2020-03-04	3	3	-	NA	-
40	Site 2	50	Female	NP	mild	2020-03-05	1	1	-	NA	-
41	Site 2	20	Female	NP	mild	2020-03-05	2	2	-	NA	-



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42	Site 2	64	Female	NP	mild	2020-03-05	1	1	-	NA	-
43	Site 2	80	Female	NP	mild	2020-03-05	1	1	-	NA	-
44	Site 2	38	Male	OP	mild	2020-03-05	1	1	-	NA	-
45	Site 2	28	Female	OP	NA	NA	NA	NA	-	NA	-
46	Site 2	58	Male	OP	mild	2020-03-07	1	1	-	NA	-
47	Site 2	31	Male	OP	mild	2020-03-06	2	2	-	NA	-
48	Site 2	57	Male	OP	NA	NA	NA	NA	-	NA	-
49	Site 2	60	Female	OP	mild	2020-03-07	1	1	-	NA	-
50	Site 2	13	Male	NP	mild	2020-03-07	1	1	-	NA	-
51	Site 2	48	Female	NP	NA	NA	NA	NA	-	NA	-
52	Site 2	68	Female	NP	NA	NA	NA	NA	-	NA	-
53	Site 2	59	Male	OP	NA	NA	NA	NA	-	NA	-
54	Site 2	59	Male	NP	mild	2020-03-09	1	1	-	NA	-
55	Site 2	59	Male	OP	mild	2020-03-09	1	1	-	NA	-
56	Site 2	57	Female	OP	NA	NA	NA	NA	-	NA	-
57	Site 2	49	Male	NP	mild	2020-03-10	0	0	-	NA	-
58	Site 2	41	Female	OP	mild	2020-03-09	1	1	-	NA	-
59	Site 2	49	Male	OP	mild	2020-03-10	0	0	-	NA	-
60	Site 2	29	Female	NP	mild	2020-03-09	1	1	-	NA	-
61	Site 2	67	Male	NP	NA	NA	NA	NA	-	NA	-
62	Site 2	68	Female	OP	NA	NA	NA	NA	-	NA	-
63	Site 2	46	Female	OP	NA	NA	NA	NA	-	NA	-
64	Site 2	80	Male	OP	NA	NA	NA	NA	-	NA	-
65	Site 2	39	Female	NP	NA	NA	NA	NA	-	NA	-
66	Site 2	60	Female	NP	mild	2020-03-10	1	1	-	NA	-
67	Site 2	76	Male	OP	NA	NA	NA	NA	-	NA	-



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Clinical sample number	Site	Age	Gender	Sample Type	Symptoms (mild/severe)	Time of symptom onset	Days between symptom onset and specimen collection for Rapid test	Days between symptom onset and specimen collection for PCR test	PCR test result	PCR Ct Value	Rapid test result
68	Site 2	58	Female	NP	NA	NA	NA	NA	-	NA	-
69	Site 2	36	Male	OP	NA	NA	NA	NA	-	NA	-
70	Site 2	28	Male	NP	mild	2020-03-11	2	2	-	NA	-
71	Site 2	22	Male	NP	mild	2020-03-11	1	1	-	NA	-
72	Site 2	25	Male	OP	NA	NA	NA	NA	-	NA	-
73	Site 2	11	Male	OP	NA	NA	NA	NA	-	NA	-
74	Site 2	38	Male	NP	NA	NA	NA	NA	-	NA	-
75	Site 2	26	Female	NP	NA	NA	NA	NA	-	NA	-
76	Site 2	58	Male	OP	NA	NA	NA	NA	-	NA	-
77	Site 2	60	Female	OP	NA	NA	NA	NA	-	NA	-
78	Site 2	30	Male	NP	NA	NA	NA	NA	-	NA	-
79	Site 2	54	Female	OP	mild	2020-03-13	2	0	-	NA	-
80	Site 2	46	Female	OP	NA	NA	NA	NA	-	NA	-
81	Site 2	46	Female	NP	NA	NA	NA	NA	-	NA	-
82	Site 2	46	Male	NP	NA	NA	NA	NA	-	NA	-
83	Site 2	12	Female	OP	NA	NA	NA	NA	-	NA	-
84	Site 2	54	Female	NP	mild	2020-03-14	2	2	-	NA	-
85	Site 2	67	Female	NP	mild	2020-03-14	2	2	-	NA	-
86	Site 2	27	Male	OP	NA	NA	NA	NA	-	NA	-
87	Site 2	76	Male	NP	NA	NA	NA	NA	-	NA	-
88	Site 2	40	Female	OP	NA	NA	NA	NA	-	NA	-
89	Site 2	60	Male	OP	NA	NA	NA	NA	-	NA	-
90	Site 2	50	Male	NP	NA	NA	NA	NA	-	NA	-
91	Site 2	65	Male	OP	mild	2020-03-17	1	1	-	NA	-
92	Site 2	48	Female	NP	mild	2020-03-16	2	2	-	NA	-
93	Site 2	70	Female	OP	NA	NA	NA	NA	-	NA	-



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94	Site 2	70	Female	NP	NA	NA	NA	NA	-	NA	-
95	Site 2	71	Male	OP	NA	NA	NA	NA	-	NA	-
96	Site 2	64	Female	NP	NA	NA	NA	NA	-	NA	-
97	Site 2	49	Male	NP	NA	NA	NA	NA	-	NA	-
98	Site 2	44	Female	OP	NA	NA	NA	NA	-	NA	-
99	Site 2	44	Female	NP	NA	NA	NA	NA	-	NA	-
100	Site 2	42	Male	OP	NA	NA	NA	NA	-	NA	-
101	Site 2	37	Female	NP	mild	2020-03-16	2	2	-	NA	-
102	Site 2	67	Male	NP	mild	2020-03-16	3	1	-	NA	-
103	Site 2	83	Male	NP	mild	2020-03-16	2	2	-	NA	-
104	Site 2	36	Female	NP	NA	NA	NA	NA	-	NA	-
105	Site 2	36	Female	OP	NA	NA	NA	NA	-	NA	-
106	Site 2	49	Female	OP	NA	NA	NA	NA	-	NA	-
107	Site 2	12	Male	NP	mild	2020-03-19	2	2	-	NA	-
108	Site 2	52	Female	OP	NA	NA	NA	NA	-	NA	-
109	Site 2	57	Female	OP	NA	NA	NA	NA	-	NA	-
110	Site 2	53	Female	OP	NA	NA	NA	NA	-	NA	-
111	Site 2	37	Male	NP	mild	2020-03-20	2	0	-	NA	-
112	Site 2	76	Male	OP	NA	NA	NA	NA	-	NA	-
113	Site 2	40	Female	OP	NA	NA	NA	NA	-	NA	-
114	Site 2	67	Male	OP	NA	NA	NA	NA	-	NA	-
115	Site 2	82	Female	OP	mild	2020-03-21	2	2	-	NA	-
116	Site 2	29	Female	OP	mild	2020-03-21	2	2	-	NA	-
117	Site 2	45	Female	NP	mild	2020-03-21	2	0	-	NA	-
118	Site 2	47	Male	NP	NA	NA	NA	NA	-	NA	-
119	Site 2	30	Male	NP	NA	NA	NA	NA	-	NA	-



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Clinical sample number	Site	Age	Gender	Sample Type	Symptoms (mild/severe)	Time of symptom onset	Days between symptom onset and specimen collection for Rapid test	Days between symptom onset and specimen collection for PCR test	PCR test result	PCR Ct Value	Rapid test result
120	Site 2	33	Male	NP	NA	NA	NA	NA	-	NA	-
121	Site 2	54	Male	OP	NA	NA	NA	NA	-	NA	-
122	Site 2	74	Female	OP	NA	NA	NA	NA	-	NA	-
123	Site 2	38	Female	NP	mild	2020-03-22	2	2	-	NA	-
124	Site 2	30	Female	NP	NA	NA	NA	NA	-	NA	-
125	Site 2	40	Female	NP	NA	NA	NA	NA	-	NA	-
126	Site 2	50	Female	OP	NA	NA	NA	NA	-	NA	-
127	Site 2	40	Female	OP	NA	NA	NA	NA	-	NA	-
128	Site 2	80	Male	NP	mild	2020-03-23	1	1	-	NA	-
129	Site 2	65	Male	NP	NA	NA	NA	NA	-	NA	-
130	Site 2	57	Male	OP	NA	NA	NA	NA	-	NA	-
131	Site 2	54	Female	NP	NA	NA	NA	NA	-	NA	-

- b) Data analysis for Rapid Response™ COVID-19 Antigen Rapid Test Device for Site 1.
- a) 52 samples presented positive results and 33 samples presented negative results using the rapid test
 - b) 41 positive samples (out of 41 PCR positive) with Ct<30
 - c) 11 positive samples (out of 14 PCR positive) with Ct≥30
- c) Data analysis for Rapid Response™ COVID-19 Antigen Rapid Test Device for Site 2.
- a) 131 of 131 PCR negative samples presented expected negative results
 - b) No false positives were observed

Table 1: Oropharyngeal Swab Specimen vs. RT-PCR Positive

Days from onset of symptoms	PCR positive	Rapid Response™ COVID-19 Antigen Rapid Test		
		Antigen Positive	PPA	95% Confidence Interval
≤7	6	6	100.00%	51.68% to 100%
8-14	24	22	91.67%	71.52% to 98.54%
≤14	30	28	93.33%	76.49% to 98.83%

Table 2: Nasopharyngeal Swab Specimen vs. RT-PCR Positive

Days from onset of symptoms	PCR positive	Rapid Response™ COVID-19 Antigen Rapid Test		
		Antigen Positive	PPA	95% Confidence Interval
≤7	4	4	100.00%	39.57% to 100%
8-14	21	20	95.24%	74.13% to 99.75%
≤14	25	24	96.00%	77.67% to 99.79%

Table 3: Oropharyngeal and Nasopharyngeal Swab Specimen vs. RT-PCR Positive

Days from onset of symptoms	PCR positive	Rapid Response™ COVID-19 Antigen Rapid Test		
		Antigen Positive	PPA	95% Confidence Interval
≤7	10	10	100%	65.55% to 100%

8-14	45	42	93.33%	80.69% to 98.26%
≤14	55	52	94.55%	83.93% to 98.58%

Table 4: Summary of Rapid Response™ COVID-19 Antigen Rapid Test Clinical Evaluation:

		RT-PCR		Total
		Positive	Negative	
Rapid Response™ COVID-19 Antigen Rapid Test	Positive	52	0	52
	Negative	3	161	164
Total		55	161	216

Relative Sensitivity: 94.55 % (83.93%~98.58%) *

Relative Specificity: 100 % (97.1%~100%)*

Overall Agreement: 98.61% (95.66%~99.64 %)*

*95% Confidence Interval

6 CONCLUSION

Based on the data obtained from these clinical investigations, the Rapid Response™ COVID-19 Antigen Rapid Test Device has proven to be an effective rapid test for the detection of SARS-CoV-2 viral antigens for up to two weeks after symptom onset.